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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Venkataraman BRINGI et al.) Group Art Unit: 1651
Serial No.: 09/083,198) Examiner: I. Marx
Filed: May 22, 1998)
For: ENHANCED PRODUCTION OF TAXOL AND TAXANES BY CELL
CULTURES OF *TAXUS* SPECIES

Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

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**SUBMISSION UNDER 37 C.F.R. § 1.607
AND 37 C.F.R. § 1.608(a)**

Sir:

On June 16, 1999, in a telephone interview with Dr. Laurence H. Posorske, Examiner Marx pointed out the potential for an interference between the above-referenced application to Bringi et al. ("Bringi") and U.S. Patent No. 5,637,484 to Yukimune et al. ("Yukimune").¹ Examiner Marx requested additional information concerning the Bringi application in view of the potential interference. Applicants believe this submission, alone or in combination with previous submissions by Applicants, provides the Examiner with the requested information and satisfies the requirements of Rule 607 and Rule 608(a). Should the Examiner feel additional information is necessary, Applicants invite the Examiner to contact the undersigned.

¹ Yukimune issued on June 10, 1997. Bringi filed this application, and has claimed the invention set forth in the proposed count, less than one year after issuance of Yukimune. Therefore, Bringi has satisfied the requirement of 35 U.S.C. § 135(b).

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I. PROPOSED COUNT

Applicants believe that certain claims in Bringi interfere with the claims of Yukimune because these claims are encompassed by the following proposed count:

A method for producing taxanes, which comprises:
culturing tissues or cells of a plant belonging to the genus *Taxus* which produce taxanes in the presence of at least one jasmonic acid; and recovering said taxanes from the resulting culture.

(A copy of the proposed count is attached on a separate sheet.) This proposed count is a paraphrase of claims 1 and 3 in Yukimune and represents substantially the same subject matter as claim 3 in Bringi, which was of record on or prior to June 10, 1998. Specifically, the term "taxanes" is substituted for the terms "taxane ring containing alkaloid compound" and "taxane-diterpene" in claims 1 and 3 of Yukimune, respectively, while the term "at least one jasmonic acid" is substituted for the phrase "jasmonate-related compounds" in claim 3 of Bringi. Use of these terms in the respective specifications is discussed in more detail below.

In Bringi, the term taxanes is used "to describe a diterpenoid compound with a taxane ring." Specification of Bringi, Page 10, Lines 8-9. According to Yukimune, "[t]he taxane-type diterpene . . . is not particularly limited to any diterpene as far as it has a taxane skeleton." Specification of Yukimune, Col. 2, Lines 27-29. Additionally, according to Bringi, "[t]otal taxanes identified in *Taxus* cultures include, among others, 10-deacetyl baccatin III, 9-dihydrobaccatin III, 7-epi-10-deacetyl baccatin III, baccatin III, 9-dihydro-13-acetyl baccatin III, 7-xylosyl-10-deacetylcephalomannine, 7-xylosyl-10-deacetyl taxol, 7-epibaccatin III, 10-deacetyl taxol, 7-xylosyl taxol, cephalomannine, 7-epi-10-deacetyl taxol, taxol, 2-benzoyl-2-

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deacetyl-1-hydroxybaccatin I, taxol C, 7-epitaxol, and 2-benzoyl-2-deacetylbaccatin I." Specification of Bringi, Page 42, Lines 24-30. According to Yukimune, "taxane-type diterpene . . . include[s] taxol, 7-epitaxol, baccatin III, 7-epibaccatin cephalomannine, 7-epicephalomannine, 10-deacetybaccatin III, 10-deacetylcephalomannine, 10-deacetyltaxol, taxagifine, an analogue thereof, taxane 1a, an analogue thereof, xylosyl cephalomannine, xylosyl taxol and the like. Further, in Yukimune, the terms "taxol ring containing alkaloid compound" and "taxane diterpene" were introduced in response to the first Office Action as a synonym for taxane-type diterpene. Yukimune's Response to Office Action, June 28, 1996, Page 6, Second Full Paragraph. Thus, the terms taxane, taxane diterpene, and taxol ring containing alkaloid compound relate to substantially overlapping subject matter.

In Bringi, "[J]asmonate-related compounds include jasmonic acid and its alkyl esters, such as methyl jasmonate, ethyl jasmonate, propyl jasmonate, butyl jasmonate, pentyl jasmonate, hexyl jasmonate; dihydrojasmonic acid and its alkyl esters, such as methyl dihydrojasmonate, ethyl dihydrojasmonate, n-propyl dihydrojasmonate, butyl dihydrojasmonate, pentyl dihydrojasmonate, hexyl dihydrojasmonate; epimethyl jasmonate, fluoromethyl jasmonate, cis-jasmone, isojsmone, tetrahydrojsmone, 12-oxophytodienoic acid, dihydrojsmone, jasmonyl acetate, apritone, amylcyclopentenone, hexylcyclopentenone, hexylcyclopentanone, and related derivatives and analogs". Specification of Bringi, Page 28, Lines 18-25. The specification of Yukimune from col. 2, line 50 to col. 7, line 54, provides chemical formulas for a range of homologous compounds characterized as "jasmonic acids." These formulas include jasmonic acid and the analogs, cucurbitic acid and tuberonic acid, as well

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as their alkyl esters and various derivatives. Yukimune then states that "[a]ll of the jasmonic acids shown above have the effect of improving the productivity in the taxane-type diterpene production". Specification of Yukimune, Col. 7, Lines 54-57. Thus, the terms jasmonic acid and jasmonate-related compounds relate to substantially overlapping subject matter.

II. CLAIMS CORRESPONDING TO THE PROPOSED COUNT

A. Yukimune Patent

Claims 1-65 of Yukimune correspond to the proposed count. Claims 1 and 3 of Yukimune both claim essentially the same thing with a minor variation in the language used to recite the product taxanes, i.e., "taxane ring containing alkaloid compound" (claim 1) and "taxane diterpene" (claim 3). Specifically, these claims are drawn to a method of producing taxanes by culturing *Taxus* cells in the presence of a jasmonic acid. Claim 2 contains the same limitations as claim 1, with a further recitation concerning the gaseous atmosphere of the culture. Because claims 4-65 depend directly or indirectly from claims 1, 2, or 3, and the Examiner who allowed Yukimune held that all claims 1-65 regard "one single general inventive concept having the same technical relationship,"² all claims 1-65 correspond to the proposed count.

B. Bringi Application

At least claim 3 of Bringi corresponds to the proposed count. Claim 1 of Bringi generally describes suspension cultures of plant cells of a *Taxus* species for the purpose of producing taxanes, with the further requirement that the method is improved by including one or

² Examiner's Action in Yukimune, January 23, 1996, Page 2, Lines 9-11 (restriction requirement).

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more enhancement agents in the culture. Dependent claim 3 further limits the method by requiring the addition of a jasmonic acid as the enhancement agent. Thus, claim 3 of Bringi corresponds to the proposed count.

Claims 1-2, 27-30, 32-34, 37-52, 55-58, 60-61, and 65 of Bringi clearly do not correspond to the proposed count because these claims do not include a recitation of "culture in the presence of a jasmonate-related compound." However, some of these claims correspond to claims of Yukimune that were restricted out of Yukimune according to the Examiner's Action dated January 23, 1996. Therefore, these claims of Bringi may correspond to the subject matter of a divisional application of Yukimune (if one has been filed) and thus, could become the subject of a separate interference.

III. BENEFIT OF EARLIER FILING DATE

Bringi is entitled to an effective filing date of February 20, 1992 for the subject matter of the proposed count. The first paragraph of Bringi states:

This application is a continuation-in-part application of International Application PCT/US97/08907 (designating the U.S.) filed May 27, 1997; and a continuation-in-part of U.S. Serial No. 08/653,036, filed May 24, 1996, which is a continuation-in-part of U.S. Serial No. 08/370,494, filed January 9, 1995, which is a divisional of U.S. Serial No. 07/874,344, now U.S. Patent No. 5,407,816, filed April 24, 1992, which is a continuation-in-part of U.S. Serial No. 07/839,144, filed February 20, 1992.

Specification of Bringi, Page 1, Lines 3-10. Thus, claim 3 of Bringi properly claims priority from:

- (i) U.S. Serial No. 08/653,036, filed May 24, 1996;
- (ii) U.S. Serial No. 08/370,494, filed January 9, 1995;
- (iii) U.S. Serial No. 07/874,344, filed April 24, 1992, now U.S. Patent No. 5,407,816, issued April 18, 1995; and

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(iv) U.S. Serial No. 07/839,144, filed February 20, 1992 ("the '144 Application").

The proposed count requires culture of a *Taxus* species in the presence of a jasmonic acid. Bringi's earliest filed parent application, the '144 Application, identifies components which are taught to be beneficial when added to a culture of a *Taxus* species, one of the components being a jasmonic acid: methyl jasmonate.³ See Table 1(c). Further, the use of a jasmonic acid, such as methyl jasmonate, as being beneficial when added to a culture of a *Taxus* species, is carried throughout all of the priority applications of Bringi.

Applicants also note that the earliest English language application present in the U.S. Patent and Trademark Office file for Yukimune is the English translation of the PCT application, which was filed under 35 U.S.C. § 371 on July 14, 1995. In accordance with 35 U.S.C. § 365(c) and 37 C.F.R. § 1.55, Yukimune is only entitled to the filing date of its PCT application, November 9, 1994, unless Yukimune files English language translations of the Japanese applications to which priority is claimed. Even if such translations were filed, the earliest date Yukimune could be entitled to if it were granted priority to its earliest claimed foreign priority date under 35 U.S.C. § 119 would be November 15, 1993.

IV. RULE 608(a) STATEMENT

With respect to the proposed count, Bringi is entitled to an effective filing date of

³ Although there was originally a typographical error in the spelling of methyl jasmonate in Table 1(c) of the parent application of Bringi that ripened into U.S. Patent No. 5,407,816, the typographical error has been corrected in the patent by a Certificate of Correction and corrected by subsequent amendment in the then pending priority application.

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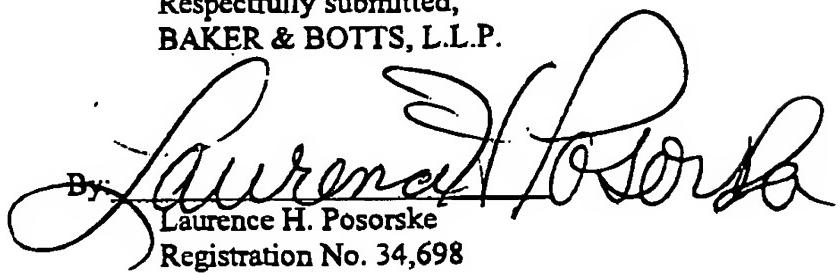
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February 20, 1992 while Yukimune, at best is entitled to a date no earlier than November 15, 1993. Therefore, Bringi is entitled to judgment relative to Yukimune.

Accordingly, Applicants respectfully request that prosecution of the subject application include consideration of the above statements in accordance with Rule 607 and 608(a).

Respectfully submitted,
BAKER & BOTTS, L.L.P.

By: 
Laurence H. Posorske
Registration No. 34,698

Date: July 19, 1999

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COPY**PROPOSED COUNT**

A method for producing taxanes, which comprises:

culturing tissues or cells of a plant belonging to the genus *Taxus* which produce
taxanes in the presence of at least one jasmonic acid; and
recovering said taxanes from the resulting culture.

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Date: August 12, 1999 Total # of Pages: 10 Including Cover

• MESSAGE •

The attached Submission Under 37 C.F.R. §1.607 and 37 C.F.R. §1.608(a) was filed on July 19, 1999 (see Postcard copy, which is date stamped). This copy is being faxed per telephone request of Examiner Marx.

If we can be of further assistance, please do not hesitate to contact me directly @ (202) 661-7520 or Laurence H. Posorske, Esq. @ (202) 639-7739.

Joy Clay
 Secretary to Laurence H. Posorske

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PATENT

Serial No. 109/083,198

Client/Matter #021652038

Filed: May 22, 1998

Client: FLYON INC.

Applicant(s): Venkataraman BRINGAL et al.

TITLE: Enhanced Production of Taxol and Taxanes By

Cell Cultures of *Taxus* Species

The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon.

> Submission Under 37 C.F.R. § 1.607 and 37 C.F.R. § 1.608(a)

Dated: July 19, 1999

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